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510(K) Summary

JUL 17 2006

Smith & Nephew Modular Femoral Heads

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	May 2, 2006
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Modular Femoral Heads
COMMON OR USUAL NAME:	Artificial Hip Replacement Prosthesis
CLASSIFICATION NAME:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360
DEVICE CLASS:	Class II
PANEL CODE:	KWL – prosthesis, hip, hemi-, femoral, metal Orthopedics Panel/87

A. INTENDED USE:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

B. DEVICE DESCRIPTION:

New cobalt chrome (CoCr) modular femoral heads have been designed and developed by Smith & Nephew Orthopaedics. The subject devices are offered in sizes ranging from 38-58mm and feature a 12/14 taper interface to allow the components to be used in conjunction with existing Smith & Nephew femoral components. The overall designs of the components are based upon existing Uni-polar implants subject of K896580.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Modular Femoral Heads are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Uni-Polar Head (K896580)
- Smith & Nephew Global Bipolar System (K023743)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

Smith & Nephew, Inc.
% Mr. Gino J. Rouss, MS
Orthopaedics Division
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K061243
Trade/Device Name: Smith & Nephew Modular Femoral Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: May 1, 2006
Received: May 3, 2006

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061243

Device Name: Smith & Nephew Modular Femoral Heads

Indications for Use:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
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Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061243